REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of the Claims

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier. It is acknowledged that the claim amendments are submitted after final rejection of the claims. However, because these amendments do not introduce new matter, and because they either place the application in condition for allowance or at least in better condition for consideration on appeal, entry thereof is respectfully requested.

Claims 17-19, 21, 22, 39-42, 44, and 45 are requested to be cancelled without prejudice or disclaimer.

Claims 1 and 47 are currently being amended. Support for these claims can be found throughout the specification as-filed, including the original claims and pages 33-34.

Claims 52-54 are being added. Support for these claims can be found throughout the specification as-filed. Exemplary support for claims 52 and 53 can be found in original claim 23, and exemplary support for claim 54 can be found in the first full paragraph of page 15.

After amending the claims as set forth above, claims 17-19, 21-22, 39-42, and 44-45 are requested to be cancelled, and claims 8, 10-16, 30, 32-38, and 46 are withdrawn. Thus, claims 1-7, 9, 17-29, 31, and 39-45, and 47-54 are pending and subject to examination.

II. Claim Rejections – 35 U.S.C. § 112, First Paragraph – Enablement

A. Claims 1-7, 9, 17-23, 31, 39-45, and 47-51

Claims 1-7, 9, 17-23, 31, 39-45, and 47-51 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. According to the Office Action, "the specification, while being enabling for a method of treating a benign tumor, a malignant tumor, hyperplasia, hypertrophy, overgrowth of a tissue and malformation of a tissue in a patient requiring removal or destruction of cells comprising locally administering (e.g. topically, intratumorally) to a mammal in need a therapeutically effective amount of the neural thread protein consisting of SEQ ID NO. 10, does not reasonably provide enablement for a method of treating any and all conditions in a patient requiring removal or destruction of cells comprising systemically administering (e.g. intravenously, intra-arterially, intraperitoneally) to a mammal in need of a therapeutically effective amount of any and all neural thread protein (NTP) as well as fragments, variant, derivative, homolog, reverse-D peptide, and enantiomers of NTP is maintained." Office Action at ¶ 8. Applicant respectfully traverses this ground of rejection.

The specification in view of the prior art contains a complete description of how to make and use the claimed invention as discussed in detail in Applicant's amendment of May 8, 2006. For example, the prior art contains detailed teachings of NTP and how to make NTP, as summarized on pages 5-6 and 9-11 of the specification. Derivatives, variants, homologs, and other forms of NTP that retain their biological activity can also be made using routine techniques well-known in the prior art, such as conservative amino acid substitutions (*see e.g.*, pgs. 11-18). The specification also contains an extensive listing of conditions requiring destruction or removal of cells (*see e.g.*, pgs. 33-34) and particular dosage forms for the NTP depending on the desired routes of administration (*see e.g.*, pgs. 36-41). Thus, the specification contains an extensive description of how to make and use the claimed invention.

The teachings of the specification are corroborated by actual working examples. The examples demonstrate that NTP induced acute necrosis regardless of the type of tissues tested or

its origin. These examples confirm that NTP can be used to treat the full scope of conditions requiring removal or destruction of cells.

The Office Action argues that "[n]either the art nor the instant specification teach a method of treating any and all conditions in a patient requiring removal or destruction of cells comprising systemically administering to a mammal in need a therapeutically effective amount of any and all neural thread protein." Office Action at pg. 6 (emphasis original). Thus, the Office Action appears to find fault in the claims for encompassing "any and all conditions in a patient requiring removal or destruction of cells," "systemic administration," and "any and all neural thread protein." The specification, however, does support the full scope of the claimed invention.

1. "Any And All Conditions In A Patient Requiring Removal Or Destruction Of Cells"

The claimed invention recites a method of treating a condition in a patient requiring removal or destruction of cells. The specification teaches and the working examples confirm that exposing tissue to NTP kills the tissue. In fact, the examples demonstrate that NTP induced acute necrosis regardless of the type of tissues tested or its origin. Because the conditions to be treated all require removal or destruction of cells, one of skill in the art would expect that the NTP could be used to treat the full scope of these conditions.

The Office Action also states that "[i]t has not been shown by administering NTP systemically to bacterially infected patients, the bacteria can be selectively removed or destructed in the patients." Office Action at 7. Claim 1 has been amended to make clear that the cells to be removed or destroyed are the patient's own cells. Thus, the method does not include destroying bacteria and viruses that have infected a patient.

Applicants note that claim 47 has been amended to recite specific conditions requiring removal or destruction of cells. These conditions include the conditions listed on page 7 of the

Office Action as enabled conditions. Thus, even if the Office persists in rejecting claim 1, the rejections to claim 47 should be withdrawn.

2. "Systemic Administration"

The specification teaches how to make and use examples of NTP compositions that can be administered systemically, such as site-specific NTP compositions (pgs. 34-36). Such compositions are well-known in the art as evinced by the ten representative references cited on pages 21-22 of Applicant's May 8th amendment. For example, chemotherapeutic agents can be delivered as conjugates to make the agents site specific. In addition, antibodies to NTP are known (pg. 10, ¶ (c)), and methods of making antibodies to specific targets are known in the art. Thus, the specification need not describe specific methods of making site-specific NTP conjugates, because a "patent need not teach, and preferably omits, what is well known in the art." MPEP § 2164.01.

The Office Action argues that "the specification fails to teach how to make such conjugates that is tumor- or site specific and the activity of NTPs is shut down or inhibited during delivery and turned on only at required sites." Office Action at 7. This is incorrect. One of skill in the art could make site-specific conjugates of NTP based on the guidance provided in the specification and techniques well-known in the art, as discussed above. Indeed, Applicant has cited ten references demonstrating the routine preparation of site specific conjugates. In addition, the activity of NTP does not need to be "shut down or inhibited during delivery and turned on only at required sites." There is no evidence that exposure to NTP results in instant cell death. Thus, active site-specific NTP conjugates could be delivered to practice the claimed invention with inhibiting the activity of NTP. Such active conjugates could be used because the NTP does not instantly kill cells contacted.

Even if the Office persists in rejecting claim 1, the rejection of claim 47 should be withdrawn. Claim 47 recites that "NTP is administered at the site of the cells requiring removal or destruction." Thus, claim 47 specifies the type of administration.

3. "Any And All Neural Thread Protein"

The specification describes in detail different forms of NTP (pgs. 5-6 and 9-11) and how to make additional forms of NTP, such as derivatives, variants, homologs, and other forms of NTP that retain their biological activity (*see e.g.*, pgs. 11-18). For example, pages 5-6 of specification cite a variety of references that describe NTP and its function, and pages 8-11 of the specification list specific examples of NTP. Other NTPs could readily be obtained by the skilled artisan using routine techniques, such as the conservative amino acid substitutions described in the specification on page 12-13, for example. Based on this detailed disclosure, a skilled artisan could readily make and use the full scope of NTPs, including derivatives, homologs, and variants.

The Office Action argues that "the specification fails to provide the guidance on how to make such broad class of molecules having the same function as the NTP of SEQ ID NO.10." Office Action at 8. The specification does provide such guidance, as discussed above. In addition, the specification states that NTPs other than SEQ ID NO: 10 will have the same activity. Indeed, the activity of all NTPs would be expected to be similar based on its similar structure and activity in other contexts. No evidence has been provided to dispute the belief that other forms of NTP would exhibit effects comparable to SEQ ID NO: 10.

Even if the Office persists in rejecting claim 1, the rejection of claims 48, 52, and 54 should be withdrawn, because these claims recite specific types of NTP.

For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

B. Claims 17-19, 21, 22, 39-42, 44, and 45

Claims 17-19, 21, 22, 39-42, 44, and 45 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. *See* Office Action at ¶ 9.

While not acquiescing in the propriety of the rejection, Applicant has canceled these claims. Thus, the amendment renders the rejection moot.

III. Claim Rejections – 35 U.S.C. § 112, First Paragraph – Enablement

A. Claims 17-19, 21, 22, 39-42, 44, and 45

Claims 17-19, 21, 22, 39-42, 44, and 45 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. *See* Office Action at ¶ 10.

While not acquiescing in the propriety of the rejection, Applicant has canceled these claims. Thus, the amendment renders the rejection moot.

B. Claims 23-29, 31, 39-45, 47, and 49-51

Claims 23-29, 31, 39-45, 47, and 49-51 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. *See* Office Action at ¶ 11. According to the Office Action, "[a]lthough the instant specification teaches a general method for making peptide mimetics, homologs, variants, etc., it fails to provide information regarding the structures of any fragments, homologs, variants, derivatives, peptide mimetics, reverse-D peptides, and enantiomers, that is correlating with the claimed function, i.e., capable of removing or destruction of cells." Office Action at pg. 14. Applicant respectfully traverses this ground of rejection.

The specification contains an extensive description of NTPs, including a variety of specific sequences and references to scientific literature describing NTP (*see e.g.*, pgs. 9-11), as discussed in detail in Applicant's May 8th amendment. For example, Figures 1-9 each list an example of a specific NTP, and an entire section is dedicated to describing the preparation of NTP, including fragments, homologs, variants, derivatives, peptide mimetics, reverse-D peptides, and enantiomers of NTP (pgs. 19-32). Based on this description, one of skill in the art could

readily make and use different NTPs, including homologs and variants, such as by using well-known conservative amino acid substitutions. Thus, one of skill in the art would readily understand Applicant to be in possession of the claimed invention.

The Office Action argues that "[t]he specification provides neither a representative number of fragments, homologs, variants, derivatives, peptide mimetics, reverse-D peptides, and enantiomers of nor does it provide a description of structural and functional features that are common to the fragments, homologs, variants, derivatives, peptide mimetics, reverse-D peptides, and enantiomers of the SEQ ID NO.10." Office Action at 14. However, the specification need not provide specific examples of the different forms of NTP, such as fragments and enantiomers. Fragments can be readily obtained based on known NTP amino acid sequences disclosed in the specification, and enantiomers are simply forms of NTP in which one or more L-amino acids are replaced by one or more of the corresponding D-amino acids, which are well-known compounds. Thus, the enantiomers do not require literal recitation. These forms of NTP could be readily screened to determine biological activity using the tests provided in the specification. *See Ex parte Mark*, 12 USPQ.2d 1904 (BPAI 1989) (holding that screening peptides for biological activity does not constitute undue experimentation). In addition, the specification does not need to provide specific examples of structural characteristics, because NTPs are a well-known class of compounds. A skilled artisan could assess structural similarity using techniques described on pages 15-16 of the specification. Therefore, the specification contains a description sufficient to describe the full genus of NTPs.

Even if the Office persists in rejecting claim 1, the rejection of claims 48, 52, and 54 should be withdrawn, because these claims recite specific types of NTP.

For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

IV. Double Patenting

A. Rejection Over U.S. Patent No. 6,924,266

Claims 1-7, 9, 47, and 49-51 stand rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 4-7 of U.S. Patent No. 6,924,266. According to the Office Action, "[b]ecause the SEQ ID Nos 23-26, 28, 29 and 52 recited in '266 patent are species of the instantly claimed genus of NTP protein, the tumor of '266 patent is a species of the genus of condition that is claimed in the instant application, and the active steps of the instant claims comprise only administering an effective amount of NTP to a mammal, therefore, claims 4-7 of U.S. Patent NO. 6,924,26682 anticipate instant claims 1-7, 9,47, and 49-51." Office Action at ¶ 12. Applicant respectfully traverses this ground of rejection.

"A double patenting rejection of the obviousness-type is 'analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103' except that the patent principally underlying the double patenting rejection is not considered prior art." MPEP § 804(B)(1). Because the underlying patent is not considered prior art, "the disclosure of the patent may not be used as prior art" when determining whether the claimed invention is an obvious variation. *Id.*

Here, the '266 patent claims a "method of treating a benign or malignant tumor in a mammal comprising local administration of a therapeutically effective amount" of one of the specifically defined NTPs recited in claim 1. The Office Action argues that the disclosure of these particular species of NTP and species of conditions would render the claimed invention obvious. However, one of skill in the art could not extrapolate from the claims of the '266 patent that NTPs in general could be used to treat "a condition in a patient requiring removal or destruction of cells," as claimed. Indeed, agents for the treatment of tumors do not necessarily treat all conditions requiring removal or destruction of cells nor do structurally similar compounds always have the same activities. Thus, the claimed invention is not merely an "obvious variation" of the cited claims of the '266 patent.

For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

B. Rejection Over Co-Pending Applications

Claims 1-7, 9, 47, and 49-51 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over "claims 12-16 and 18 of copending Application No. 10/294,891 and claims 9-13 and 15 of copending Application No. 10/920,313." Office Action at ¶ 13.

Applicant notes the provisional nature of this rejection and will address the rejection on the merits if it ever matures into a non-provisional rejection.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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